

REMARKS

Claims 1-18 of the subject application are pending. Applicants have amended claims 1 and 2, for improved readability. No substantive change has been made by this amendment, and entry is appropriate since no additional search will be required and the claims, as amended, will be in a better form if an appeal is necessary.

Claims 1 and 2 stand finally rejected, while claims 3-18 have been described as not anticipated or rendered obvious by the art of record, and therefore allowable.

The rejection of claim 2 has been based on 35 U.S.C. § 112, second paragraph, but this statute requires only that the applicants particularly point out and distinctly claim the subject matter that the applicants regard as being their invention. Unquestionably, this has been done: the rejected claims relate to a single known chemical compound, in a new amorphous form. The term "amorphous" is well known to those skilled in the art. The scope of the claims is not so large that those skilled in the art would have any amount of difficulty in determining exactly what is included within the claim.

Further, the applicants have specifically incorporated into claim 2 the X-ray diffraction pattern of Fig. 1, which is typical of amorphous compounds in that it shows only a broad halo rather than a series of sharp diffraction peaks. The language presented herein for claim 2 places it in correspondence with related claims in a large number of very recently granted patents, including U.S. Patent 6,831,091 B2 to Gant et al.; claims 2, 6, 10, 14, 18, 22, and 26 of the Gant et al. patent each are directed to a salt, or polymorphic form of a salt, of a previously known compound, the invention being defined solely by the diffraction pattern in a drawing figure.

The rejection under 35 U.S.C. § 112 should not be maintained, upon reconsideration.

Claim 1 has been rejected under 35 U.S.C. § 103(a) as being rendered obvious by European Patent Application 0 496 307 A1, in view of U.S. Patent 4,820,833 to Crisp et al. or Chapter 5 of Cheronis' "Semimicro Experimental Organic Chemistry," 1958, the

Office Action stating that "there is no patentable distinction in the concept of a compound in amorphous or crystalline form."

However, this statement ignores literature that has been made of record in the file of this application, namely the article by A. Goho that was submitted with the applicants' response on July 20, 2005. The article discusses the total uncertainty that exists with regard to the existence of polymorphic forms of drug compounds, and the necessity for identifying as many of the polymorphic forms as possible, when they can be found. The article also points out the commercial importance of drug polymorphs.

The Office Action appears to justify the obviousness rejection by asserting that the applicants' amorphous form was suggested to one skilled in the art, "from the expectation of obtaining a pharmaceutically useful benefit..." This appears to be an assertion that it would be obvious to try to make a polymorphic form of sumatriptan succinate, since some drugs are known to have polymorphic forms having desirable properties. Such reasoning is not a legally proper foundation for a holding of obviousness under current legal principles, such as taught by *In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988), a decision that is cited in numerous unpublished decisions of the Board of Patent Appeals and Interferences plus a few published decisions such as *Ex parte Obukowicz*, 27 U.S.P.Q.2d 1063, (Bd. Pat. App. & Interf. 1992).

Applicants do not agree that one skilled in the art, setting out to find a new polymorphic form of a drug compound, would have a reasonable expectation of success, given the discussion present in the previously mentioned article by Goho. The law requires a reasonable expectation of success, as a prerequisite for obviousness. See *In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988). This expectation must be founded in the prior art.

It remains a fact that no combination of the applied documents discloses or suggests the existence (or possibility) of an amorphous form of sumatriptan succinate. As explained by M.P.E.P. § 706.02(j), in the absence of a disclosure or suggestion of each claim limitation, there can be no *prima facie* case for obviousness. If no *prima facie* case has been established, then applicants are not required to produce any further evidence in support of patentability.

The Office Action cited the decision *In re Weijlard, Stiller and Levy*, 154 F.2d 133, 69 USPQ 86 (CCPA 1946) in support of the rejection. This was an affirmation of a rejection of claims to crystalline, nonhygroscopic calcium pantothenate, and a process for preparing it that involved crystallization from a lower alcohol. The art of record disclosed precipitation of calcium pantothenate from a lower alcohol (however, apparently also involving isopropyl ether) to form an amorphous, hygroscopic product, and the examiner had considered the claimed product to be merely a more pure form of the product in the art.

Weijlard is not in accord with the present common practice of the Office to grant patents for polymorphic forms of drug compounds, and does not take into consideration the general current knowledge of those skilled in the art that polymorphism is totally unpredictable and that the discovery of new drug polymorphs is very important for patient safety. Current law clearly holds that each limitation of a claim must be present or suggested in the art, before obviousness can properly be held, and there is nothing in *Weijlard* to indicate that this principle was considered. Under more recent legal principles, such as was expressed by the court of *In re Wakefield and Foster*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970), the *Weijlard* claims would be considered as being patentable over the applied art, since the lack of hygroscopicity could not have been predicted.

Also cited in the Office Action was *In re Cofer*, 354 F.2d 664, 148 USPQ 268 (CCPA 1966). In this decision, the rejection of claims to free-flowing crystals of 2,2-bis (2,3-epoxypropoxyphenyl) propane was reversed, because there was no evidence in the references or common knowledge to establish obviousness. There is a quotation at 271, attributed to the prior decision *Ex parte Hartop*, 139 USPQ 525 (P.O. Bd. App. 1962), as follows:

... merely changing the form, purity or another characteristic of an old product, the utility remaining the same as that for the old product, does not render the claimed product patentable...

and the CCPA described the *Hartop* decision and other decisions as holding unpatentability "where the alleged difference in form or purity of those substances was either disclosed or inherent in, or rendered obvious by, the prior art of record," and therefore failing to support the broad proposition of the quoted language. As stated by

the CCPA at 271, "Merely stating that a compound or composition is obvious, without adequate factual support, is not sufficient." *Cofer* does not support the present rejection, and it seems that the *Weijlard* claims would have been found to be unobvious by the *Cofer* court.

The rejection of applicants' claim 1 for obviousness is not in compliance with current legal principles, and should not be maintained.

CONCLUSION

In view of the foregoing Amendment and Response, applicants request reconsideration, withdrawal of the final rejections, and an early Notice of Allowance for all claims pending in this application.

Applicants request that the Examiner telephone the undersigned attorney, should the Examiner have any questions or remaining issues that might be expeditiously resolved by a telephonic or personal interview. No fee is believed necessary in connection with the filing of this Response. If any fee is required, however, authorization is hereby given to charge the amount to Deposit Account No. 50-3221.

Respectfully submitted,



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